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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,547

12/12/2003

Rich Ewers

USGINZ02511

2408

40518

7590

09/25/2008

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,547	Applicant(s) EWERS ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19, 32-36 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-19, 32-36, and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 11-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Deem et al. (6,558,400). Deem et al. disclose, at least in figure 28 and col. 19, lines 35-54; a method of endoscopically forming, approximating and securing a plurality of tissue folds (e.g., 480), the method including advancing an anchor delivery device (478) through the patient's esophagus into the patient's stomach; endoscopically forming a first tissue fold; placing a first anchor (482) across the tissue fold; forming at least one additional tissue fold, thereby forming the plurality of tissue folds; placing at least one additional anchor (482) across the at least one additional tissue fold; approximating the plurality of tissue folds (i.e., moving the folds closer together to reduce the volume of the stomach); and securing the approximated plurality of tissue folds with the anchors, where the first tissue fold and the at least one additional tissue fold are not attached to one another, and where the first tissue fold is formed from an anterior segment of the patient's stomach and the at least one additional tissue fold is from a posterior segment, and where the tissue folds are disposed inferior to the patient's gastroesophageal junction.

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Deem et al. also disclose a method of performing gastric reduction procedure including endoscopically forming, approximating and securing a first plurality of tissue folds in a first plane within a patient's stomach, and endoscopically forming, approximating and securing at least one additional plurality of tissue folds in at least one additional plane within the patient's stomach (where the planes are tangential to the outer surface of the esophagus), where the first plane and the at least one additional plane are substantially parallel to one another, where the first plurality of tissue folds are not attached to one another, where the first plurality of tissue folds and the at least one additional plurality of tissue folds each comprise at least one tissue fold from an anterior segment of the patient's stomach and at least one tissue fold from an opposing posterior segment, where the first plurality of tissue folds and the at least one additional plurality of tissue folds are disposed inferior to the gastroesophageal junction

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 32-36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deem et al. (6,558,400) in view of Matsui et al. (6,352,503). Deem et al. disclose the invention substantially as claimed. Deem et al. disclose, at least in figures 6A-6E and col. 8, line 56 to col. 10, line 7; a method of performing endoluminal gastric reduction, where the method includes advancing a plication apparatus (e.g., an endoscopic vacuum-type device 280 as seen in figure 15A) within a patient's stomach; approximating and deploying tissue anchors (110) through each of first and second pluralities of tissue folds in respective first and second planes (to form a smaller pouch), where the tissue folds comprise anterior and posterior segments of the patient's stomach, and where the tissue folds are disposed inferior to the gastroesophageal junction. However, Deem et al. do not disclose an overtube disposed in a flexible state; transitioning the overtube to a rigid state in a desired orientation comprising an arc traversing at least about 180 deg., where the plication apparatus is advanced through a first lumen of the overtube and a gastroscope is advanced through a second lumen. Matsui et al. teach, at least in figures 23 and 44-47 and in col. 11, line 50 to col. 12, line 5 and col. 17, lines 23-45; a method of performing endoluminal gastric reduction including advancing an overtube (101) through a patient's esophagus into the patient's stomach while the overtube is disposed in a flexible state; transitioning the overtube to a rigid state (at 111) in a desired orientation comprising an arc traversing at least about 180 deg. within the patient's stomach and approximating and securing first and second

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pluralities of tissue folds in respective first and second planes (at 187), where the method includes advancing a plication apparatus (186) through a first lumen in the overtube and a gastroscope (light guide) through a second lumen (at 114) contained in the overtube. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Matsui et al., to apply a plication apparatus, an overtube, and a gastroscope as claimed in the method of Deem et al. Such modifications would ease access of these tools into the stomach and allow visualization of the stomach as tissue is folded and anchored.

5. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deem et al. (6,558,400) in view of Matsui et al. (6,352,503), and further in view of Harrison (5,403,326). Deem et al. in view of Matsui et al. disclose the invention substantially as claimed, but do not disclose that the desired orientation of the overtube comprises an arc traversing approximately 270 deg. Harrison teaches, at least in figure 8A, an overtube (58) having an orientation comprising an arc traversing approximately 270 deg. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Harrison, to modify the overtube of Deem et al. in view of Matsui et al., so that it can be oriented as claimed. Such an orientation would allow the overtube to access and visualize tissues in difficult-to-reach locations for the formation of tissue folds.

Response to Amendment

6. Applicant's arguments with respect to claims 11-19, 32-36, and 38-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

September 25, 2008